

**IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF VIRGINIA
Roanoke Division**

KIMBERLY BROWN,)	
)	
Plaintiff,)	
)	
v.)	
)	
NEW ENGLAND COMPOUNDING)	
PHARMACY, INC. d/b/a)	
NEW ENGLAND)	
COMPOUNDING CENTER,)	Civil Action No. 7:12-cv-584-SGW
)	
and)	
)	
IMAGE GUIDED PAIN)	
MANAGEMENT, P.C. d/b/a)	
INSIGHT IMAGING ROANOKE,)	
)	
Defendants.)	

**IMAGE GUIDED PAIN MANAGEMENT, P.C.’S
MEMORANDUM IN SUPPORT OF ITS
MOTION TO DISMISS PLAINTIFF’S COMPLAINT**

COMES NOW Defendant Image Guided Pain Management, P.C. d/b/a Insight Imaging Roanoke (“IGPM”),¹ by counsel, and for its Memorandum in Support of Motion to Dismiss to Plaintiff’s Complaint, states:

FACTS

Plaintiff claims that she visited IGPM in Roanoke, VA and received an injection of methylprednisolone acetate to treat her spinal pain. (Compl. ¶ 17.) Plaintiff alleges that the injection she received contained a fungus that can cause fungal meningitis. (*Id.*

¹ At all times relevant hereto, IGPM was a Virginia professional corporation consisting of two physician shareholders who practiced medicine at 2923 Franklin Road Southwest, Roanoke, VA 24014. The name of the clinic where IGPM’s physicians practiced was Insight Imaging—Roanoke. IGPM neither owns nor manages such clinic. Instead, that clinic is owned and managed by InSight Health Corporation (“Insight”). Insight is a Delaware corporation with offices across the United States and its principal place of business in Minneapolis, Minnesota.

¶¶ 18–19.) According to Plaintiff’s Complaint, the methylprednisolone acetate was manufactured by the New England Compounding Pharmacy, Inc d/b/a New England Compounding Center (“NECC”)—also a named defendant in this suit. NECC allegedly delivered the methylprednisolone to Insight’s clinic in Roanoke, VA. Plaintiff asserts that after receiving the injection, she began experiencing symptoms consistent with fungal meningitis and has sought medical treatment to address those symptoms. (*Id.* ¶ 20.) Based on these facts, Plaintiff has filed suit against IGPM and NECC, asserting claims for breach of express and implied warranties.

STANDARD OF REVIEW

A complaint needs “a short and plain statement of the claim showing that the pleader is entitled to relief and sufficient “[f]actual allegations ... to raise a right to relief above the speculative level....” *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (internal quotation marks omitted). A plaintiff’s basis for relief “requires more than labels and conclusions....” *Id.* Therefore, the plaintiff must “allege facts sufficient to state all the elements of [the] claim.” *Bass v. E.I. Dupont de Nemours & Co.*, 324 F.3d 761, 765 (4th Cir.2003).

However, determining whether a complaint states a plausible claim for relief is “a context-specific task that requires the reviewing court to draw on its judicial experience and common sense.” *Ashcroft v. Iqbal*, — U.S. —, 129 S.Ct. 1937, 1950 (May 18, 2009). Thus, a court screening a complaint under Rule 12(b)(6) can identify pleadings that are not entitled to an assumption of truth because they consist of no more than labels and conclusions. *Id.*

Jones v. Akers, 2011 WL 4102317, *1 (W.D. Va. Sept. 14, 2011)

ARGUMENT

I. IGPM is a service provider, not a seller, and therefore not subject to products liability claims for treatment rendered.

In her Complaint, Plaintiff describes IGPM as being “engaged in the business of providing medical and/or related *services*, specifically including but not limited to radiological imaging and the administration and/or injection of drugs” (Compl. ¶ 3) (emphasis added). Yet Plaintiff also repeatedly characterizes IGPM as a “seller” and “merchant” with regard to the methylprednisolone acetate injection Plaintiff received. (Compl. ¶¶ 22, 31.) It is the latter characterization of IGPM upon which Plaintiff relies to assert her breach of warranty claims. (Compl. ¶¶ 21–41.)

Yet Virginia law is clear that if an entity purely is a service provider, it cannot also be a seller with regards to a products liability action. A “threshold question” when determining whether a warranty action can lie “is whether the transaction was one for the sale of goods or the provision of services.” *AAF-McQuay, Inc. v. MJC, Inc.*, 2002 WL 172442, *3 (W.D.Va. 2002). The Uniform Commercial Code (“U.C.C.”), as adopted by Virginia, applies to transactions in goods, not services. Va. Code. § 8.2-102. In order to establish warranty claims against IGPM, Plaintiff must be able to show that IGPM is a seller of goods under the U.C.C. *See* Va. Code §§ 8.2-313–15 (setting forth the requirements for establishing express and implied warranties). If the defendant “is a professional providing services . . . the law of warranty does not apply.” *Gressman v. Peoples Service Drug Stores, Inc.*, 10 Va. Cir. 397 (Richmond Cir. Ct. Feb. 9, 1988) (citing *Vann v. Harden*, 188 Va. 555, 565, 47 S.E.2d 314 (1948); *Gagne v. Bertran*, 43 Cal.2d 481, 487, 275 P.2d 15 (1954); *J. O. Morry Stores v. Skoog Constr. Co.*, 38 Ill.App.3d 747, 348 N.E.2d 474 (1976). “Whether the U.C.C. applies turns on a question

as to whether the contract . . . involved principally a sale of goods, on the one hand, or a provision of services, on the other.” *Coakley v. Williams*, 706 F.2d 456, 459 (4th Cir. 1983). “Thus, before applying the U.C.C., courts generally examine the transaction to determine whether the sale of goods predominates.” *Princes Cruises, Inc. v. General Elec. Co.*, 143 F.3d 828, 832 (4th Cir. 1998).

IGPM is engaged in the business of providing medical services, not the business of selling methylprednisolone acetate. IGPM provides patients with radiological services and only administers medicine as a part of the overall treatment service. Courts in Virginia and across the United States have held that entities involved in the provision of medical treatment provide their patients with services and are not “sellers” or “merchants” under the U.C.C.

Even in situations where a defendant does, in fact, sell drugs directly to the purchaser, where it occurs in the context of medical treatment Virginia courts have held that an action in warranty cannot be sustained. In *Gressman v. Peoples Service Drug Stores, Inc.*, 10 Va. Cir. 397 (Richmond Cir. Ct. Feb. 9, 1988), the plaintiff visited the defendant pharmacy to have a prescription for chlorpromazine filled. *Id.* at *1. The pharmacy mistakenly filled plaintiff’s prescription with chlorpropamide, not chlorpromazine. *Id.* Plaintiff subsequently ingested the incorrect medication, which caused her severe injuries, brain damage and “rendered her semi-comatose.” *Id.* Plaintiff, though her Guardian, sued the defendant pharmacy in a products liability action, asserting claims for breaches of express warranty and implied warranties of merchantability and fitness for a particular purpose. *Id.*

Defendant demurred to the warranty claims, arguing that “a pharmacist is not a merchant selling goods, but is a professional providing services” and therefore the warranty claims could not lie. *Id.* at *6. The Court looked to the Virginia Code (the “Code”) for guidance on whether to classify the pharmacy as a seller or service provider. The Code defined the “practice of pharmacy” as a “health service” “concerned with the art and science of” preparing and dispensing “drugs, medicines and devices used in the diagnosis, treatment, or prevention of disease” Va. Code. § 54-524.2. In addition, the Code defined “health care” as

[A]ny act, or treatment performed or furnished, or which should have been performed or furnished, by any health care provider for, to, or on behalf of a patient during the patient’s medical diagnosis, care, treatment or confinement.

Va. Code § 8.01-581.1. The Court observed that, by reading the two Code provisions together, the defendant pharmacy was engaged in providing health care:

Since a pharmacist is unquestionably a “health care provider,” and since the delivery of a prescription drug is unquestionably and “act,” the delivery of a prescription drug to a patient by a pharmacist is unquestionably “health care.”

Gressman, 10 Va. Cir. 397, at *8. The Court reasoned further that the pharmacist’s actions of preparing prescriptions are not “simply for their own edification,” but are instead undertaken “in order to dispense.” *Id.* Because the “sale of a prescription drug by a pharmacist is necessarily ‘health care . . . it is not a ‘sale’ within the meaning of the Uniform Commercial Code, and the court so holds.” *Id.* The Court accordingly sustained the defendant’s demurrer to plaintiff’s warranty claims. *Id.*

In *Coffman v. Arthrex, Inc.*, 69 Va. Cir. 17 (August Co. Cir. Ct. March 31, 2005), plaintiff was admitted to the Augusta Medical Center for surgery to repair a torn rotator

cuff. *Id.* at *1. During the procedure, a biodegradable screw was inserted into plaintiff's shoulder. *Id.* The screw was manufactured and sold to the defendant medical center by co-defendant Arthrex, Inc. *Id.* Subsequent to plaintiff's surgery, the screw failed, thereby necessitating additional surgical procedures. *Id.*

Plaintiff sued the defendant medical center and product manufacturer on breach of warranty theories. *Id.* As with the present matter, "[n]owhere is there an allegation of negligence, and nowhere is there an allegation that any employee of [defendant medical center] breached any standard of care." *Id.* The defendant medical center demurred to plaintiff's warranty claims, arguing that it was a service provider, not a seller or merchant of goods. *Id.* *2. In a brief opinion, the Court sustained the demurrer. "The Court is of the opinion that health care providers render a service to their patients, and the transfer of any type of good or device to the patient during treatment is merely incidental to that treatment." *Id.* The Court reasoned that "had the General Assembly intended health care providers to be treated as 'merchants,' such a provision would have been covered in the Medical Malpractice Act. It clearly is not." *Id.* The Court concluded, "[t]he health care provider is not a 'seller' and is not subject to liability on a products liability theory."

Though the Supreme Court of Virginia has not examined a case that is directly on point, their reasoning in *Commonwealth of Virginia Dept. of Taxation v. Bluefield Sanitarium, Inc.*, 216 Va. 686, 222 S.E.2d 526 (1976), a tax case, is instructive. There, the Supreme Court of Virginia had to determine whether a private hospital was exempt from sales tax on the hospital's bulk purchase of drugs from the drug manufacturers and wholesalers. *Id.* at 687, 222 S.E.2d at 527. The drug at issue was one that the hospital dispensed to its patients. *Id.* The Court ruled that the Hospital was a consumer of the

drug, not a retailer, and therefore was not exempt from the tax at issue. *Id.* at 689, 222 S.E.2d at 528.

In so ruling, the Supreme Court of Virginia made important observations that are relevant to the case at bar. The Court noted that “[a] hospital is engaged primarily in rendering services, and the meals, drugs bandages, etc. provided its patients are incidental to the rendition of theses services.” *Id.* at 688, 222 S.E.2d at 528. The Court also remarked that “[n]o taxable event occurs with respect to drugs supplied by the hospital to the patient, for such drugs are being supplied and administered in the performance of its service as a hospital.” *Id.* at 689, 222 S.E.2d at 528. “Irrespective of whether the hospital is providing beds, food or medicines, the hospital is the ‘consumer’ in the tax sense because all property acquired by it is for use in the performance of its service to patients.” *Id.* Thus, in *Bluefield Sanitarium* the Supreme Court of Virginia directly examined whether a health care provider was a service provider or a seller of goods and held that the “service provider” classification was correct. Applying such logic to the case at bar compels the conclusion that IGPM is likewise a service provider and therefore not subject to products liability claims.

Other jurisdictions are in agreement with Virginia that health care providers render services and cannot be subjected to products liability claims based on the administration of medicine incidental to the service rendered. In *Royer v. Catholic Medical Center*, 144 N.H. 330, 741 A.2d 74 (1999), the Supreme Court of New Hampshire was confronted with a plaintiff’s product liability claims against a hospital arising from a defective prosthetic knee. *Id.* at 331, 741 A.2d at 75. The defendant moved to dismiss, arguing that it was not a “seller of goods” and therefore not subject to

the product liability claims. *Id.* The Court noted at the outset that “[i]f the defendant merely provides a service, however, there is no liability absent proof of a violation of a legal duty.” *Id.* at 332, 741 A.2d at 76.

The Court then reviewed the law of other jurisdictions and observed that “[a] majority of the jurisdictions” that have addressed the issue have dismissed products liability claims against health care providers, “similarly reasoning that the health care provider primarily renders a service, and that the provision of a prosthetic device is merely incidental to that service.” *Id.* at 333, 741 A.2d at 76–77 (citing *Cafazzo v. Cent. Medical Health Services*, 542 Pa. 526, 668 A.2d 521, 524–25 (1995); *In re Breast Implant Product Liability*, 331 S.C. 540, 503 S.E.2d 445, 448–51 (1998); Annotation, *Liability of Hospital or Medical Practitioner under Doctrine of Strict Liability in Tort, or Breach of Warranty, for Harm Caused by Drug, Medical Instrument, or Similar Device used in Treating Patient*, 65 A.L.R. 5th 357, 387-96 (1999) (collecting cases).

The Court then framed the issue as “not whether the defendant ‘sold’ or transferred a prosthetic knee, but whether the defendant was an entity ‘engaged in the business of selling’ prosthetic knees so as to warrant the imposition of liability without proof of legal fault.” *Id.* at 333, 741 A.2d at 77. “The thrust of the inquiry is thus not on whether a separate consideration is charged for the physical material used in the exercise of medical skill, but what service is performed to restore or maintain the patient’s health.” *Id.* at 334, 741 A.2d at 77 (quoting *Cafazzo v. Cent. Medical Health Servs.*, 542 Pa. 526, 529, 668 A.2d 521, 524 (1995)). The Court then reasoned that “it is evident that [plaintiff] entered [the hospital] not to purchase a prosthesis, but to obtain health care

services that included the implantation of the knee, with the overall objective of restoring his health.” *Id.* at 334, 741 A.2d at 78.

Public policy implications were also central to the Court’s ruling in *Royer*. “Because ‘ordinarily there is no possibility that a distributor other than the manufacturer created a design defect[,] . . . strict liability would impose liability when there is no possibility of negligence.’” *Id.* at 335, 741 A.2d at 78 (quoting *Parker v. St. Vincent Hosp.*, 122 N.M. 39, 919 P.2d 1104, 1108–09). “Further, holding health care providers strictly liable for defects in prosthetic devices necessary to the provision of health care would likely result in higher health care costs borne ultimately by all patients[.]” *Id.* (citing *Ayyash v. Henry Ford Health Systems*, 210 Mich.App. 142, 533 N.W.2d 353, 355 (1995); *Parker*, 919 P.2d at 1108; *Cafazzo*, 668 A.2d at 527). This imposition of liability would “‘place an unrealistic burden on the physicians and hospitals of this state to test or guarantee the tens of thousands of products used in hospitals by doctors.’” *Id.* (citing *Ayyash*, 522 N.W.2d at 356; *Parker*, 919 P.2d at 1110). Additionally, “research and innovation in medical equipment and treatment would be inhibited” if products liability actions could be maintained against the service provider. *Id.* (citing *Cafazzo*, 668 A.2d at 527; *Hoff v. Zimmer, Inc.*, 746 F.Supp. 872, 874–75). The Court concluded that the “peculiar characteristics of medical services . . . outweigh any reasons that might support the imposition of strict liability in this context.” *Id.*

This Court should follow the majority rule as applied in Virginia precedent and in persuasive authority from across the United States. Plaintiff’s complaint correctly asserts that IGPM was “engaged in the business of providing medical and/or related *services*, specifically including but not limited to radiological imaging and the administration

and/or injection of drugs” at the time it treated Plaintiff. (Compl. ¶ 3.) The injection Plaintiff received was a part of that *medical service*, and even if the Court agreed with the Plaintiff that IGPM sold the injection to plaintiff, such sale was merely ancillary to the service IGPM provided. It was even further removed from the context of a “sale of a product” than was the situation in the *Gressman* case discussed above, which held that even in that more direct context the fact that the transfer of the drug to the Plaintiff occurred in the medical services context rendered the Plaintiff’s warranty claim deficient. IGPM is not a “seller” or “merchant” subject to products liability warranty claims. This Court should, in accordance with Virginia precedent and the majority rule of other jurisdictions, dismiss Plaintiff’s claims against IGPM for failure to state a claim upon which relief could be granted.

II. Plaintiff’s failed to comply with the provisions of Virginia’s Medical Malpractice Act.

Virginia’s Medical Malpractice Act (the “Act”) provides for certain procedures associated with claims brought against health care providers. Virginia Code § 8.01-20.1 requires that plaintiffs, for any medical malpractice action, certify that an expert has reviewed their claims and provided a written opinion that the defendant deviated from the standard of care. Va. Code. § 8.01-20.1. Virginia Code § 8.01-581.1 defines malpractice as “any tort action *or breach of contract action* for personal injuries or wrongful death, based on health care for professional services rendered, or which should have been rendered, by a health care provider, to a patient.” Va. Code. § 8.01-581.1 (emphasis added). As described in Plaintiff’s Complaint, IGPM renders health care services and qualifies as a health care provider under the Act. *See* (Compl. ¶¶ 3, 17); Va. Code § 8.01-581.1 (defining “Health care provider” and “health care”).

Claims for breach of express or implied warranties sound in contract. *See, e.g., Burner v. Ford Motor Co.*, 52 Va. Cir. 301 (Prince William Co. Cir. Ct. June 7, 2000) (noting that plaintiff's breach of implied warranty claims were "contractual" and implicated the statute of limitations period applicable to contracts). Malpractice is defined to include "breach of contract actions." Va. Code 8.01-581.1. IGPM is a health care provider subject to the requirements of the Act. (Compl. ¶¶ 3, 17); Va. Code § 8.01-581.1. The act sets forth pre-suit certification requirements for any malpractice action against health care providers. Va. Code § 8.01-20.1. Plaintiff's Complaint is devoid of any certification that an expert reviewed plaintiff's claims and provided the requisite written opinion. Consequently, Plaintiff's Complaint is deficient under the Code and must be dismissed.

III. Under Virginia law, health care providers are not responsible for the compounding of medicine.

Under Virginia law, pharmacists, not health care providers, are responsible for supervising the compounding process, "which shall include a final check for accuracy and conformity to the formula of the product . . . appropriate conditions and procedures, and appearance of the final product." Va. Code § 54.1-3410.2(D). Additionally, it is the pharmacist's responsibility, not the responsibility of the treating health care provider, to "ensure compliance with USP-NF standards for . . . sterile . . . compounding." Va. Code § 54.1-3410.2(E).

The Complaint is clear that the source of Plaintiff's alleged injuries were the alleged defects in the methylprednisolone acetate that Plaintiff received via injection. Therefore, under the Code, there are no facts set forth in the Complaint which could implicate liability on behalf of any health care provider, including IGPM. Under the facts

set forth in the Complaint, Plaintiff visited IGPM for treatment and IGPM injected Plaintiff with a drug which IGPM received after that drug was supposed to have undergone the appropriate tests for purity and safety.

IGPM's physicians must be able to rely on the statutory scheme which obligates those who provide drugs to IGPM to ensure those drugs are safe. Any other scheme would result in an unduly burdensome set of requirements whereby IGPM and other health care providers would have to independently test all drugs they administer. Such a requirement would cripple the administration of medicine and undermine the effective treatment of patients. As the Supreme Court of New Hampshire observed in *Royer v. Catholic Medical Center*, "holding health care providers strictly liable for defects in [medical goods] necessary to the provision of health care would likely result in higher health care costs borne ultimately by all patients[;] . . . place an unrealistic burden on the physicians and hospitals" and inhibit "research and innovation in medical equipment and treatment." *Royer*, 144 N.H. at 335, 741 A.2d at 78 (internal citations omitted). This Court should not impose liability against IGPM for responsibilities that the Virginia legislature has vested elsewhere.

IV. Even if the U.C.C. applied to IGPM—which it does not—Plaintiff fails to allege sufficient facts to support a claim for breach of express warranty or implied warranty of fitness for a particular purpose.

Virginia Code § 8.2-313 provides the requirements for creating express warranties under the U.C.C:

(1) Express warranties by the seller are created as follows:

(a) Any affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain creates an express warranty that the goods shall conform to the affirmation or promise.

(b) Any description of the goods which is made part of the basis of the bargain creates an express warranty that the goods shall conform to the description.

(c) Any sample or model which is made part of the basis of the bargain creates an express warranty that the whole of the goods shall conform to the sample or model.

(2) It is not necessary to the creation of an express warranty that the seller use formal words such as "warrant" or "guarantee" or that he have a specific intention to make a warranty, but an affirmation merely of the value of the goods or a statement purporting to be merely the seller's opinion or commendation of the goods does not create a warranty.

Va. Code § 8.2-313. In the present matter, Plaintiff only states that IGPM “labeled, indicated, held out and/or otherwise warranted and/or represented that the dose of steroid sold to and injected into [plaintiff] was . . . suitable and appropriate” (Compl. ¶ 23.) Such allegations are wholly insufficient to establish an “affirmation of fact or promise” or any other basis for an express warranty. In *Sanders v. Medtronic, Inc.*, 2006 U.S. Dist. LEXIS 45516; 60 U.C.C. Rep.Serv.2d 342 (E.D.Va. 2006), plaintiff asserted a claim for breach of express warranty based on the sale of a medical product. *Id.* at *27. In that case, the plaintiff supported her allegations with more specific charges that what Plaintiff has asserted in the case at bar:

Plaintiff alleges in her Motion for Judgment that the defendants provided documentation to the plaintiff that stated the following: “The battery life of the pulse generator depends on the number of hours you use it each day and how strong the stimulation must be to control your pain. Your doctor can give you an estimate once your pulse generator settings have been determined.”

Id. The complaint alleged that the implanting surgeon gave an estimate of four to five years of battery life. The Court analyzed the plaintiff’s assertions and concluded they

failed to state a claim. “The problem with plaintiff’s breach of express warranty claim . . . is that the plaintiff has not alleged any facts that suggest that [defendant] made any express warranties to the plaintiff regarding the . . . devices.” *Id.* If the allegations in *Sanders* were inadequate, then the lesser allegations in this case cannot support a breach of express warranty claim.

Nor does Plaintiff adequately state a claim for breach of warranty of fitness for a particular purpose. Plaintiff simply states that IGPM breached implied warranties, “including but not limited to [an] implied warrant[y] of fitness for a particular purpose” and that the injection was “unfit for the general and particular purpose of being injected into the human body” (Compl. ¶ 34.) But mere allegations of the ordinary purpose for which goods are used are insufficient to establish a particular purpose. The Official Comment to Va. Code § 8.2-315 states, “[a] particular purpose differs from the ordinary purpose for which the goods are used in that it envisages a specific use by the buyer which is peculiar to the nature of his business whereas the ordinary purposes for which goods are used are those envisaged in the concept of merchantability and go to uses which are customarily made of the goods in question.” Va. Code § 8.2-315 cmt. 2. Allegations of ordinary purpose are insufficient to set forth a particular purpose. *Id.*; *Sanders*, 2006 U.S. Dist. LEXIS 45516; 60 U.C.C. Rep.Serv.2d 342 (E.D.Va. 2006). Plaintiff’s Complaint in this matter is completely devoid of any allegations of a *particular* purpose. Consequently, the claim for breach of implied warranty of fitness for a particular purpose should be denied.

CONCLUSION

WHEREFORE, Image Guided Pain Management, P.C. d/b/a Insight Imaging Roanoke (“IGPM”), respectfully moves this Court to Grant its Motion to Dismiss, to enter final judgment in its favor, to dismiss this action against it from the Court’s docket, to award it the costs and attorneys’ fees associated with the defense of this action, and for such other and further relief as the needs of this case may require and which this Court deems appropriate.

Respectfully submitted,

IMAGE GUIDED PAIN
MANAGEMENT, P.C.

By: s/ Michael P. Gardner

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CERTIFICATE OF SERVICE

I hereby certify that on December 27, 2012, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system, which will send notification to the following:

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